K112650 P1/3

FEB - 1 2012

510(k) Summary

Submission Date:	09 September 2011
Submitter:	Connexall USA, Inc. 5540 Central Avenue, Suite 220 Boulder, CO 80301
Submitter Contact:	Mr. John Elms Connexall USA, Inc. 5540 Central Avenue, Suite 220 Boulder, CO 80301 +1 (720) 279-8707 jelms@connexall.com
Official Contact:	Mr. Thomas Kroenke Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 +1 (303) 956-4232 tkroenke@speedtomarket.net
Manufacturing Site:	Globestar Systems Inc. 7 Kodiak Crescent, Suite 100 Toronto, Ontario, Canada M3J 3E5
Trade Name:	Connexall Suite of Software Products
Common Name:	Network and Communication Middleware
Classification Name:	System, Network And Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:

Connexall Model	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
Connexall Suite of Software Products	K102974	Philips Medical Systems / Philips Emergin Event Management System

Device Description:

The Connexall USA, Inc. (Connexall) Suite of Software Products (Software) is an on-site messaging integration solution which forwards patient monitor status and alarm information to the user via display devices provided by third-party mobile device companies. Users receive interactive, time-critical information from patient monitoring devices directly via their display devices as text, alarms or data. Connexall Software allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

Connexall Software is a client/server application designed to run under any Microsoft Windows 32-bit operating system. At the core of the application is the Notification Server. The Notification Server includes the database application, system administration, licensing, and the resources to manage the near-real-time event processing and dispatching.

The Connexall Suite of Software Products is offered in four (4) configurations. These configurations include:

- Connexall Enterprise;
- Connexall Pro;
- Connexall Care; and
- Connexall LITE.

Intended Use:

The intended use of the Connexall Suite of Software Products is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s).

For medical, near real time alarms, the Connexall Suite of Software Products is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. The Connexall Suite of Software Products does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audio and/or vibrating mechanism upon receipt of the alert.

The Connexall Suite of Software Products is intended for use as a secondary alarm. It does not replace the primary alarm function on the monitor.

Technology Comparison:

The Connexall Suite of Software Products employs the same or similar technological characteristics as the predicate device.

Performance Testing:

Software Testing	The Connexall Suite of Software Products was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Connexall Suite of Software Products complies with its predetermined specifications.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of the Connexall Suite of Software Products. The results of these activities demonstrate that the Connexall Suite of Software Products is safe and effective when used in accordance with its intended use and labeling. Therefore, the Connexall Suite of Software Products is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 1 2012

Connexall USA, Inc.
c/o Mr. Thomas Kroenke
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466

Re: K112650
Trade/Device Name: Connexall Suite of Software Products
Regulation Number: 21 CFR 876.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Codes: MSX
Dated: January 30, 2012
Received: January 30, 2012

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112650

Indications for Use

510(k) Number (if known): K

Device Name: Connexall Suite of Software Products

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112650